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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,648	02/12/2007	Masaru Tanaka	4252-0119PUS1	5783

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EXAMINER

IWAMAYE, ANDREW MICHAEL

ART UNIT	PAPER NUMBER
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3774

NOTIFICATION DATE	DELIVERY MODE
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ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/580,648	Applicant(s) TANAKA ET AL.	
	Examiner ANDREW IWAMAYE	Art Unit 3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 June 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-15 and 20-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-15 and 20-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims 11-15 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. **Claims 11, 13, 20-22, and 25** are rejected under 35 U.S.C. 102(b) as being anticipated by Patel et al (US 6,436,132).

Regarding **claims 11 and 20**, Patel et al (Patel) teaches a **stent** (i.e. **a medical instrument**) **comprising** a stent surface (i.e. **a medical instrument substrate**), and a ePTFE covering (i.e. **film**) **including a resin and having a porous structure formed at least on its surface, the surface of the medical instrument being entirely or partially covered with the film** (column 2, lines 19-49).

Regarding **claim 13**, Patel teaches the pores to have an average pore size of 10-100microns (i.e. 0.1 to 100µm.).

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Regarding **claims 21-22**, Patel teaches all of the structural limitations of claim 20. As such, the stent of Patel is inherently capable of being used as a digestive system stent, specifically a bile duct stent.

Regarding **claim 25**, Patel teaches all of the structural limitations of the claims 11 and 25. As such, the film of Patel is a cell growth inhibiting film.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

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under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. **Claims 12, 14, and 23** are rejected under 35 U.S.C. 103(a) as being unpatentable over Patel et al (US 6,436,132) in view of Nishikawa et al ("Mesoscopic patterning of cell adhesive substrates as novel biofunctional interfaces").

Regarding **claims 12 and 14**, Patel teaches all of the limitations set forth in claim 11. Patel further teaches the film to be sufficiently porous such that it is effective at preventing diseased tissue ingrowth (column 2, lines 19-49).

Patel fails to teach the porous structure of the film to be in a honeycomb structure. Patel also fails to teach the porous structure of the film to have a coefficient of variation in pore size of 30% or less.

However, Nishikawa et al (Nishikawa) teaches a film including a resin and having a honeycomb porous structure formed at least on its surface (see "Experimental" section beginning on pp 142). The film can be tailored to inhibit cellular adhesion/proliferation, specifically when the pores sizes are kept at 2microns or below (see "Conclusions" section and pp 145, first paragraph of right column).

Patel and Nishikawa are concerned with the same field of endeavor, namely films that prevent/inhibit cellular growth.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the film of Patel by incorporating a porous film with a honeycomb structure, as taught by Nishikawa, in order to provide an alternative, commonly known anti-cell-proliferation film. One would be further motivated to provide the film of Nishikawa since production of such a film is more cost-saving and technologically simpler than other production techniques ("Introduction" section).

Moreover, it would have been obvious to employ a coefficient of variation in pore size of 30% or less in order to ensure that the pore sizes remain below the threshold level of 2 microns, as taught by Nishikawa, such that the anti-adhesion properties of the film are optimized.

Regarding **claim 23**, Patel and Nishikawa teach all of the limitations. Refer to rejections as applied to claims supra. Patel further teaches the pores to be through-holes, as cells, tissue, and capillaries can penetrate through the pores to the intima (see column 2, lines 19-49).

8. **Claim 15** is rejected under 35 U.S.C. 102(b) as anticipated by Patel et al (US 6,436,132) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Patel et al (US 6,436,132) in view of Nishikawa et al ("Mesoscopic patterning of cell adhesive substrates as novel biofunctional interfaces").

Regarding **claim 15**, The Examiner recognizes claim 15 as a "product-by-process" claim. Even though product-by-process claims are limited by and defined by

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the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process (*In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966).

Since Patel teaches all of the structural limitations of the claims 11 and 15, Patel meets the limitations of the claim.

Nevertheless, Nishikawa teaches a film obtained by the claimed production steps (see "Introduction" and "Experimental" sections).

9. **Claim 24** is rejected under 35 U.S.C. 103(a) as being unpatentable over Patel et al (US 6,436,132) in view of Makoto et al (JP 2003-102849).

Regarding **claim 24**, Patel teaches all of the limitations set forth in claim 11 but fails to teach the claimed thickness.

However, Makoto et al (Makoto) teaches a stent comprising a tubular, porous film 3 (see Figures). The film is taught to be 10-200 microns thick (i.e. 0.1 to 100 microns) ([0022]).

Patel and Makoto are concerned with the same field of endeavor, namely stents with porous, tubular film covers.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the film of Patel by making it with the claimed thickness,

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as it is an obvious design choice/variation that produces predictable results of creating a physically/structurally stable film.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANDREW IWAMAYE whose telephone number is (571)270-7036. The examiner can normally be reached on Monday-Friday 7:30AM-5:00PM, with every other Friday off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on (571)272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/A. I./

Examiner, Art Unit 3774

7/30/2009

/William H. Matthews/

Primary Examiner, Art Unit 3774